8. 510(k) Summary

Submitted by:
RD Medical Manufacturing, Inc., PO Box 899, Calle Escudero Final, Bo. Fulladosa, Culebra, Puerto Rico, 00775. *Contact*: Carlos A. Rodríguez-García, Ph.D., Product Development Director.

Date of Summary:
February 19, 2001

Trade Name of Proposed Devices:
PARSET® Primary Set for Cannula and Secondary Set with Cannula

Common Name:
Infusion Sets

Classification Name:
Intravascular Administration Set (§880.5440)

Predicate Devices:
For PARSET® Primary Set for Blunt Cannula (A10003E):
PARSET® A10002E, Primary Set with Checkvalve, manufactured by RD Medical Manufacturing, Inc. (510(k) # **K001102**).

For PARSET® Secondary Set with Blunt Cannula (A14003E):
PARSET® A14001E manufactured by RD Medical Manufacturing, Inc. (510(k) # **K000017**).

Description of Proposed Devices:
The proposed administration sets will be used as a system for primary and secondary intravascular administration of fluids and medication. The proposed devices employ needleless technology for connection of primary and secondary administration sets. The proposed devices are designed to be used with collapsible fluid containers. The proposed Secondary Set (A14003E) is designed exclusively for interfacing with the proposed Primary Set (A10003E).

Intended Use:
The intended use of the proposed devices is for the intravascular administration of fluids and medication by trained health care personnel. The administration of fluids is achieved through gravity from collapsible fluid containers through venipuncture devices (not included in the proposed devices).

Summary of Technological Characteristics of Proposed Devices to Predicate Device
The proposed devices are composed of the same type of components and intended use of the predicate devices. The differences between the proposed and predicate devices follow.

Proposed Primary Set (A10003E)

- The proposed Primary Set contains injection sites (510(k) # K953343) with pre-slit septum for perforation by a plastic blunt cannula (510(k) # K952834).

Proposed Secondary Set (A14003E):

- The proposed device employs a plastic blunt cannula (510(k) # K952834) to connect to injection site (510(k) # K953343) in the PARSET® Needleless Primary Set for Blunt Cannulas, proposed Primary Set (A10003E). The predicate device employs an 18G hypodermic needle to connect to a primary set.
- The blunt cannula proposed Secondary Set is assembled to the distal connector of the secondary set; as opposed to the predicate device, which contains a needle packaged in a blister package within the device packaging.
- The blunt cannula in the proposed Secondary Set is designed to lock in place once inserted into the injection site of the proposed Primary Set (see detail in Appendix A, Engineering Drawings).

Discussion of Non-clinical Tests
Testing of the proposed devices was conducted per the Recognized Consensus Standards:

- ISO 8536-4: 1987, Infusion equipment for medical use - infusion sets for single use, gravity feed
- ANSI/AAMI/ISO 10993-1: 1997, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing
- ANSI/AAMI/ISO 11607: 1997, Packaging for terminally sterilized products
- ANSI/AAMI/ISO 11137: 1994, Sterilization of health care products- requirements for validation and routine control- radiation sterilization.

Except for the deviations noted in Appendix D, Declaration of Conformance with Recognized Consensus Standards, all data indicate that the proposed devices PARSET® Primary Administration Set for Blunt Cannula, Catalog # A10003E, and PARSET® Secondary Administration Set with Blunt Cannula, Catalog # A14003E meet or exceed all functional requirements and that the proposed devices are suitable for their intended use.

9. Truthfulness and Accuracy Statement

I certify that, in my capacity as Product Development Director of RD Medical Manufacturing, Inc., to the best of my knowledge, all data and information included in this pre-market notification are truthful and accurate and that no material fact has been omitted.

Carlos A. Rodríguez-García, Ph.D.

2/19/01
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2001

Mr. Carlos A. Rodriguez-Garcia
Product Development Director
RD Medical Manufacturing, Incorporated
Calle Escudero Final, BO.
Fulladosa
Cuelbra, Puerto Rico 00775

Re: K010538
Trade Name: Parset® Needleless Primary Set for Blunt Cannula, A10003E, Parset® Needleless Secondary Set with Blunt Cannula, Al4003E
Regulatory Class: II
Product Code: FPA
Dated: February 19, 2001
Received: February 23, 2001

Dear Mr. Garcia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010538

Indications For Use

510(k) Number (if known) K010538

Device Name: PARSET Needleless Sets

Indications For Use:

The proposed devices are a system for administration of medication and fluids intravascularly to patients through a needle inserted into the vein. The proposed Primary Set contains injection sites with pre-slit septums for use with plastic blunt cannula to eliminate the risk of needlesticks.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cascuito

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010538